Translating Hypertension Guidelines into Practice: Development of Interoperable Clinical Decision Support

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Abstract

Background: High blood pressure (HBP) affects nearly half of adults in the United States and is a major factor in heart attacks, strokes, kidney disease, and other morbidities. Patient-facing clinical decision support (CDS) tools may help patients adhere to evidence-based care but customization is required.

Objective: Our objective was to understand how to adapt CDS to best engage patients in controlling HBP.

Methods: We conducted semi-structured interviews and surveys based on HBP guidance to gather patient and care team perspectives for CDS. We analyzed this data to identify prioritized recommendations, preferences, and inputs for CDS. We then built a tool called the Collaboration Oriented Approach for Controlling HBP (COACH) that incorporated adapted recommendations and best practices for engagement using interoperable standards.

Participants. We interviewed 17 and surveyed 519 patients and 29 experts and providers.

Results: Participants were ready and willing to use technology and found enhanced displays more trustworthy (60-80% preferred over simpler displays), especially when incorporating social trust. For >150,000 patients, we found data adequacy issues, with 2/4 use-cases meeting criteria. The tool met all success criteria except minor performance issues.

Conclusion. COACH required careful adaptation of guidelines and motivators for patient engagement, however it is feasible and fills a needed gap.

Purpose of Study

Our purpose was to understand how to adapt clinical decision support (CDS) to best engage patients in controlling high blood pressure (HBP), to understand care team variations and rationales related to HBP recommendations and perceptions regarding patient role, use of digital tools, and challenges, and to study guideline-based HBP and hypertension recommendations and evaluates the suitability and sufficiency of the data and logic required for a FHIR-based, patient-facing CDS HBP application. Each subtopic had its own purpose.

Patient Perspectives Analysis: Our objective was to understand how to adapt both the CDS recommendations and the visualization and explanation of those recommendations and the related patient data to best engage patients in controlling HBP.

Provider Analysis: With providers, we sought to understand care team variations and rationales related to HBP recommendations and perceptions regarding patient role, use of digital tools, and challenges.

Data Sufficiency Analysis: This portion of the study examined guideline-based HBP and hypertension recommendations and evaluated the suitability and sufficiency of the data and logic required for a FHIR-based, patient-facing CDS HBP application.

Application Build and Test: Finally, our purpose in putting this all together was to build an interoperable, modular system that met usefulness, appropriateness, usability, and other needs identified from the above analyses. We then sought to implement and test the system to demonstrate its feasibility. We also sought to share the underlying logic, value sets, and functionality via a content-based implementation guide and to make it available to the public through AHRQ's CDS Connect.

Scope

Background

There are many challenges to controlling HBP, especially when it is diagnosed as hypertension. First, hypertension is known as the 'silent killer', [1] as elevated blood pressures are asymptomatic, leading to a lack of engagement from patients. Second, measuring blood pressure requires frequent measurements and attention to protocol to assess control; home blood pressure monitoring (HBPM) is frequently recommended yet rarely followed, leading to uncertainty about control and increased risk of adverse events from overtreatment.[2] Third, the therapeutic index in controlling blood pressure can be narrow; a large blood pressure trial, the SPRINT study, showed a 25% relative reduction in cardiovascular events in the tightly controlled blood pressure group versus less intensive (<120/80 vs 140/90, respectively) but a substantial increase in adverse events such as dizziness, falls, electrolyte disturbances and acute kidney injury.[3] Lastly, and perhaps most pressing, the role of the patient is crucial in blood pressure control: behavioral and lifestyle changes can reduce blood pressure by more than 15 mmHg in most patients.[4] Given most people lack symptoms for HBP, patient engagement and motivation remain a substantial issue.

A patient-facing tool with robust CDS – providing the right information at the right time in the right format through the right channel[5] – may afford a way to better help patients manage their blood pressure and related conditions.[6] Encouraging patients to set goals (e.g. smoking cessation, physical activity, diet and salt/sodium intake, weight, and alcohol intake) can promote patient agency and engagement in blood pressure management while also helping their care teams to obtain a more complete understanding of the patient's cardiovascular health.[7,8]

Goals and personal priorities may vary considerably, making recommendations difficult to implement. Assessing patient perceptions of priorities for goal setting is critical for designing CDS tools for engaging patients in treating HBP. Moreover, engaging people to set and follow goals requires behavioral change: behavior science has both cognitive precepts, like self-efficacy, and behavioral economics concepts such as choice architecture, structured incentives, prosocial messaging and social trust that may improve motivation and engagement.[9, 10] Choice architecture is the ordering of options or defaults to help people make decisions more easily[11] and structured incentives – like loss avoidance – help maintain motivation.[12] Social trust may be enhanced through well-sourced information and clinician recommendations.[13] Prosocial messaging encourages people to consider the beneficiaries of their behaviors when changing behaviors.[14] Focusing on others can be strong motivation: a review of older adults and people making changes after heart attack or stroke showed team-based engagement with challenges and achievements were more effective at encouraging healthy behaviors.[15-17] However, studies of behavioral science to guide CDS, especially with patients, is limited and results are mixed despite the promise.[18, 19]

Our team has developed a publicly available, shareable, patient-facing and interoperable hypertension CDS artifact according to the Fast Healthcare Interoperability Resources (FHIR) standard.[20] FHIR has led to improved electronic capabilities for information exchange, with pilots in pain management, screening, and more.[21] Our goal is to align multiple hypertension guidelines and transform a single set of recommendations into FHIR format for future implementations according to the emerging Clinical Practice Guidelines on FHIR (CPG-on-FHIR) standard.[22] However, standardization may also negatively impact workflow and decision-making when variability is called for due to differences in preferences, in the underlying data, and in the guidelines themselves. Clinical practice variability may be due to provider

interpretation of guidelines and recommendations and application to patient needs, preferences, and values, which would be reasonable; or the variability may be unwarranted. Poorly designed CDS may exacerbate the variability and worsen clinical care and increase mental fatigue, while carefully designed CDS can aid in shared decision-making.

Context

This effort is in the context of extensive evidence about the effectiveness of HBP control, but with limited implementation of HBP CDS recommendations that encompass HBP control guidelines; the evolution of interoperable capabilities, the logical language known as Clinical Quality Language, the FHIR messaging standards, and the policy requirements to open Application Programming Interfaces to patients created new opportunities to advance this CDS.

Settings

The primary implementation setting was a large academic health system with 11 primary care clinics and more than 90 specialty clinics. We also interacted with the HL7 CPG-on-FHIR and related communities, and met regularly with the CDS Connect community, including those who held similar grants.

Participants. Each sub-study had different participants:

Patient interviews and survey. Eighteen hypertensive patients were interviewed, out of 38 patients contacted, with one removed from analysis due to technical challenges preventing the interviewee from viewing the shared screen. Of the seventeen remaining participants, summarized in Table 1, all identified as white/Caucasian, with a mean age of 69.2.

In all, 541 participants completed the survey. We removed 22 incomplete responses. The 519 remaining responses are summarized in Table 1. Demographically, 260 (50.1%) participants identified as female, with a much younger mean age of 41.2 years as compared to the interviewees (69.2 years). Most participants (52.4%) were under the age of 40, with only 14.5% of participants aged 60 or older. We compared the groups (Appendix Table 1) and noted a higher burden of disease in the younger adults than is usually reported. A majority (65.0%) of participants identified as Caucasian.

*Care team survey***:** We recruited providers from a convenience sample of 17 certified Patient-Centered Primary Care Homes within Oregon[23] between June 2020 and December 2020. Providers within those clinics received an e-mail invitation that included a consent form and a link to the online survey. Providers had to have independent prescribing privileges in Oregon to be eligible. Participants received $50.00 for completing the survey.

Data adequacy: Adult patients with a diagnosis of hypertension or 4 blood pressures > 140/90 were selected from a 3.4 million patient electronic health record (EHR) dataset; patients needed to have an ambulatory visit between 2010-2018.

Incidence High blood pressure is increasing in incidence as the population ages, with almost 1% increase per year of increasing age from 45-60. Incidence is higher in Black populations at earlier ages and lower in college educated groups. More than 80% of patients meet criteria to monitor blood pressure at home.

Prevalence Current high blood pressure prevalence is estimated at 47-50% of the adult population.

Methods

Study Design

Patient interviews, survey, and care team preferences: We created a unique survey that queried providers about their attitudes toward clinical practice guidelines for hypertension and patient-facing CDS. The OHSU Institutional Review Board approved this study. We used an iterative development process that focused on the constructs of HBP guideline recommendations, variation, importance, challenges, and patient input and effort. For demographics, shared decision-making, and use of hypertension tools, we used questions from other surveys to assess these concepts.[24] For hypertension guidelines, our questions were informed by Alper's[25] synthesis of hypertension guidelines into 71 recommendations. We organized the questions into five use cases that were meant to elicit provider preferences for diagnostic, monitoring, and treatment approaches to hypertension management with a focus on variability in the guidelines. Table 1 highlights the cases and their objectives. These were altered from the care team to patients based on the results of the care team study; patients were only asked about contacting their care team in a modified version of the final cases.

Table 1. Case definitions and objectives

Case	Description	Objective
Case 1: Initial Diagnosis and Screening	Patient with no recorded history of hypertension, nonsmoker, BMI 31, pre-diabetic.	Identify approaches to initial screening and diagnosis. Would participants make the diagnosis of hypertension based on presented information or would they order additional screenings?
Case 2: Non-Pharmacologic Interventions	Patient with untreated hypertension and no comorbidities.	Identify approaches to prescribing non-pharmacologic interventions. Which lifestyle changes (diet, physical activity, etc.) would participants prioritize for patients?
Case 3: Initial Pharmacology for hypertension	Patient with untreated hypertension and no comorbidities.	Identify approaches to initial pharmacology. Which antihypertensive medication(s) would participants prescribe for first-line therapy?
Case 4: Pharmacology for Moderate hypertension	Patient with hypertension, stage 3 CKD. Currently on low-sodium diet for hypertension.	Identify approaches to initial pharmacology if patient had comorbidity. Which antihypertensive medication(s) would participants prescribe for first-line therapy?
Case 5: Pharmacology for Severe hypertension	Patient with severe hypertension, stage 4 CKD, controlled DM, prior left MCA ischemic stroke, currently taking 50mg atenolol for hypertension.	Identify approaches to modified pharmacology in severe cases of hypertension. Which antihypertensive medication(s) would participants prescribe? Would they discontinue current treatment?

The survey also asked providers to record their preferred hypertension care recommendations from four guidelines: 1) Eighth Joint National Committee (JNC 8) [26]; 2) American College of Cardiology/American Heart Association (ACC/AHA) [27]; 3) American College of Physicians (ACP/AAFP) [28]; and 4) U.S. Department of Veterans Affairs (VA) [29]. We presented providers with cases and asked them to record their preferences for various therapeutic interventions, indicate the guideline-based recommendations that most aligned with their thinking, and rate their selections by importance, frequency of use, difficulty, patient input required, and patient work required. Ratings were on a seven-point scale with

seven being the highest, one the lowest, and four as neutral. The survey also asked participants to provide free text answers as to why they made the decisions they made for each use case, as well as share their overall impressions of CDS and shared decision-making in hypertension care.
We first fielded a pilot version of the survey to a convenience sample of provider experts (n=280) who had completed the American Hypertension Specialist Certification Program [30] to assess the understandability of the questions and the reliability of the responses (See Appendix "Draft Survey"). The pilot survey resulted in a final 90-question survey, with six sections and 14-18 questions per section. The patient survey had 40 questions with most of the expert recommendation components removed.
Data sufficiency: To assess the overall adequacy of data for high blood pressure recommendations, we used Kahn et al's definitions of conformance and completeness. Conformance is defined as the degree to which "data values adhere to specified standards and formats." Completeness assesses whether the required or expected data values are present. Both data quality categories may be assessed using internal knowledge and information (verification) or external knowledge and information (validation). We evaluated data conformance by first categorizing the value sets we found or created by their previous use and curation. We then mapped the internal data sources to these value sets and compared the use of these codes in the EHR data to the set of codes available. For completeness, we first looked at the prevalence of individual concepts across a population of those with hypertension, categorizing them as completely missing, extremely low (<0.1%), or low (<1%). Where structured EHR data were available but unmapped to standard concepts, we extracted these, flagged them as nonconforming, and still measured prevalence. Then, we examined the relative prevalence or incidence of key concepts for those with diagnosed hypertension and those with HBP (meeting diagnostic criteria) without a recorded diagnosis. For use cases, we used the recommendations to develop logical steps for the CDS, using frameworks for clinical quality measures (CQMs) while adding specific requirements. CDS elements need information about the context and setting for the initial patient, then inclusion and exclusion criteria, the recommendation itself, and patient-specific context to provide more accurate decision-making. Selection of and consensus on the use-cases and value sets was done nominally through asynchronous review by the investigative team. Instead of defining an initial patient population (as in CQMs), we defined the right context or setting to present the CDS i.e., ambulatory visits. For inclusion criteria, we used the recommendation inclusion (e.g., diagnosis of hypertension and blood pressure not meeting goal). We separated criteria that may exclude patients from the recommendation to match the CQM categories. Next, we took the action or intervention implied by the recommendation and measured how many had received that intervention (akin to a numerator) and how many had not (where the recommendation would then be shown). Finally, we identified patient-specific context where the guideline identified potential variation or reasons that may influence—but not exclude—the decision to follow the recommendation.

Data sources/Collection

Patient analysis: Patients from a set of primary care clinics in Oregon and a national, online panel of adults with hypertension were included in the study. The primary care clinic patients were recruited through their providers if they had HBP; the national online panel was contracted through Qualtrics and has been used in several other HBP studies.
Care team analysis: We created a unique survey that queried providers from Oregon primary care clinics and hypertension experts nationally about their attitudes toward clinical practice guidelines for hypertension and patient-facing CDS.
Data adequacy analysis: We used the work of Alper et al.[25] to identify 71 recommendations from eight different hypertension guidelines. We then parsed these recommendations to identify key concepts

required to assess the state of these recommendations on populations and patients. To assess the status of these concepts in the EHR, we used a 5-pronged approach to identify previously used and/or validated data definitions available in EHR data and defined by FHIR. We used a combination of value sets from the Value Set Authority Center (defined and used in clinical quality measures); from CDS Connect artifacts (used in other CDS); from phenotype definitions (used and validated to identify patient cohorts); from United Medical Language System (UMLS) services, including RxNAV for medications; and through the Observational Health Data Sciences and Informatics (OHDSI ATLAS) terminology services for missing or incomplete concepts. We chose the last based on the work of Hripcsak et al for the LEGEND trial.[31] In this trial, they validated a set of encodings for key outcomes related to hypertension across a large data set. The specific mappings and value sets are available from the open source GitHub repository (https://github.com/OHDSI/Legend) for the project. We extracted data from the EHR by mimicking FHIR resource calls based on data domain. We did not use FHIR directly because we wanted the flexibility of searching for the data through nonstandard means. The resource domains included conditions that are mapped in both SNOMED with included hierarchical relationships (allowing children from the encoded SNOMED but not ancestors) and ICD codes; medications in RxNorm; observations and laboratory values in Logical Observation Identifiers Names and Codes (LOINC), and visits/utilization using SNOMED and CPT. We identified the initial populations in two ways. First, we found unique patients with the diagnosis of essential hypertension. Then, excluding those with a diagnosis, we found those with an elevated blood pressure (>140/90) taken more than twice over more than two separate visits.

Interventions and Outcomes

Interventions include two separate but interconnected systems, which are the COACH application, and the Hypertension Implementation Guide (IG).

COACH Application

A primary goal of the grant was to incorporate guidelines into recommendations in an interoperable manner that aligned with care team and provider expectations and met technical standards. The COACH application was the result of that expectation.

The COACH Application is a Java Spring-based web application that uses FHIR to retrieve patient data from an authorized FHIR server and displays that information in a curated manner to the user for the purposes of managing hypertension. Authentication is handled by the SMART-on-FHIR protocol. Launching the application must originate from either within an EHR system such as Epic (Provider-context), or from a patient-centric system such as Epic's MyChart (Patient-context). Application startup begins following a successful SMART-on-FHIR authentication handshake, at which time patient data is retrieved from the FHIR server and displayed to the user through the COACH user interface. Description of the application itself is given in the Results section of this report.

Hypertension Implementation Guide (IG)

The Hypertension Implementation Guide (IG) is an HL7 FHIR construct used to represent clinical and logical data used by the COACH application in the form of recommendations. The IG essentially displays the inner workings and logic of the COACH application with human-readable text descriptions. Description of the IG is given in Results section of this report.

Measures

Data sufficiency analysis: We evaluated data conformance by first categorizing the value sets we found or created by their previous use and curation. We then mapped the internal data sources to these value sets and compared the use of these codes in the EHR data to the set of codes available. For completeness, we first looked at the prevalence of individual concepts across a population of those with hypertension, categorizing them as completely missing, extremely low (<0.1%), or low (<1%). Where structured EHR data were available but unmapped to standard concepts, we extracted these, flagged them as non-conforming, and still measured prevalence. Then, we examined the relative prevalence or incidence of key concepts for those with diagnosed hypertension and those with high blood pressure (meeting diagnostic criteria) without a recorded diagnosis.

Limitations

Patient analysis: This research has several limitations. The population was not entirely representative of those with HBP in the United States. The population skewed younger, more technologically literate, and was less representative of underserved communities. However, this is representative of populations who would use a patient-facing CDS tool. Self-reported comorbidities require good health literacy to be accurate; our prior studies have shown reasonable accuracy in this group.[32] The rate of heart attack and stroke among adults under the age of 40 was much higher than expected; however, this group is growing rapidly.[33] Future surveys may address these concerns through health literacy screening and by stratifying survey participant subpopulations to achieve overall distributions closer to the population. Future versions of the tool could be created by engaging users historically marginalized by healthcare in a Human Centered Design process.

Care team analysis: This study has limitations that are important to note. First, we recruited providers from a convenience sample rather than a random sample;[34] however, this is common in qualitative and user acceptance designs. Second, our analysis incorporated a "top three" approach to represent priority recommendations, which has the potential to conflate priority recommendations. Also, we reported summary scores for each of the cases but due to the variety of non-responses throughout the survey, we only removed survey scores when a respondent failed to answer an entire battery of survey questions. Lastly, we did not vet our qualitative themes ("member check") based on participants' free text answers.

Data sufficiency analysis: Primary limitations include the single site's worth of data – albeit a large, complex academic health center – and adequacy of the data may be related to work processes and data capture at that site. In addition, we use queries against the proprietary data structures rather than using FHIR queries themselves; this was done in ways that directly mimicked FHIR. In practice, local EHR FHIR servers expose data differently to FHIR queries than they do for data warehouse queries, so the adequacy assessment was incomplete. Given the relative immaturity of bulk FHIR, we thought this was the wisest course. The use-cases cannot cover all scenarios, leaving out secondary diagnoses and many aspects of management. They were felt to be archetypal for home blood pressure management.

Results

Principal findings. *Patient results.* In all, 18 patients were interviewed and 519 were surveyed. The published manuscript (*Patient perspectives on enhancing clinical decision support for high blood pressure control)* with these results is in the List of Publications section and provides greater detail.

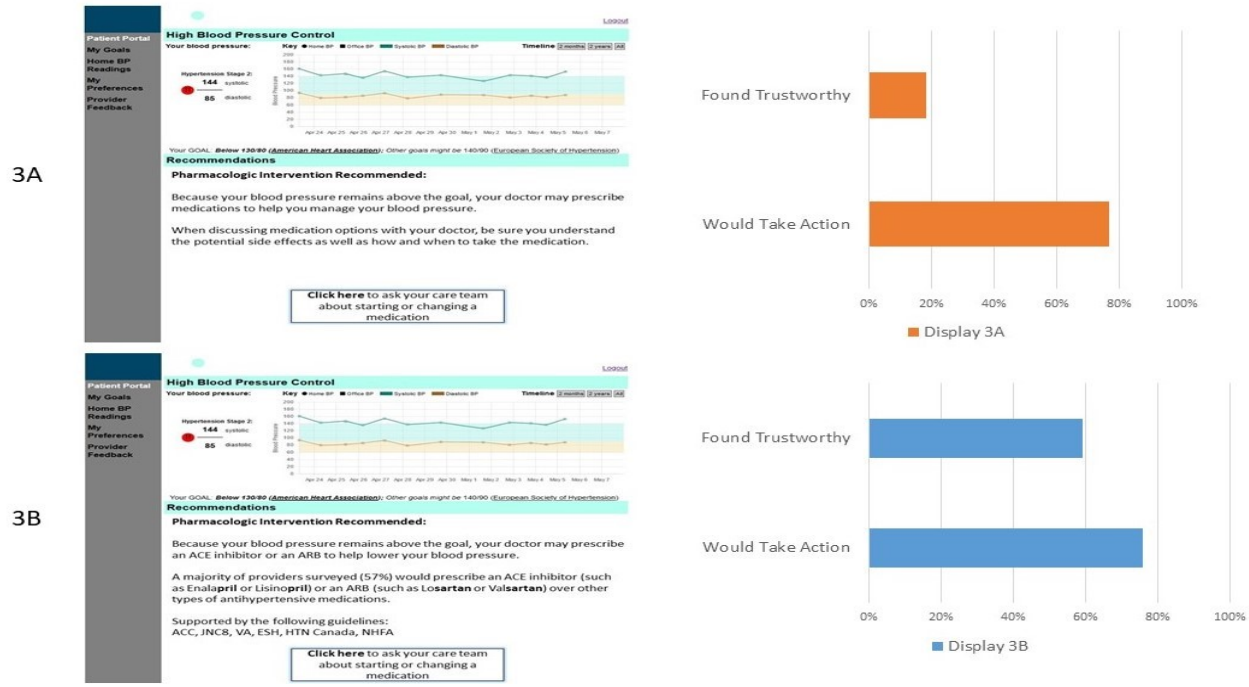

Figure 1. Perceived trustworthiness and actionability of displays by patients

Figure 1 provides an example of A/B testing of recommendation displays from the *Patient perspectives on enhancing clinical decision support for high blood pressure control* manuscript. The bottom option is information rich, providing more information including specific examples of the medications most likely to be prescribed and supporting national guidelines. A majority (58.6%) of patients found this option more trustworthy, and more patients indicated that it would likely make them take action.

Across all such examples, patients indicated a preference for more thorough information presentation, including information about blood pressure history, clinician-endorsed goals, and potential pharmacologic treatments for hypertension. Social and relational information, such as what clinicians would recommend or what other patients would do, was deemed particularly trustworthy.

Care team results

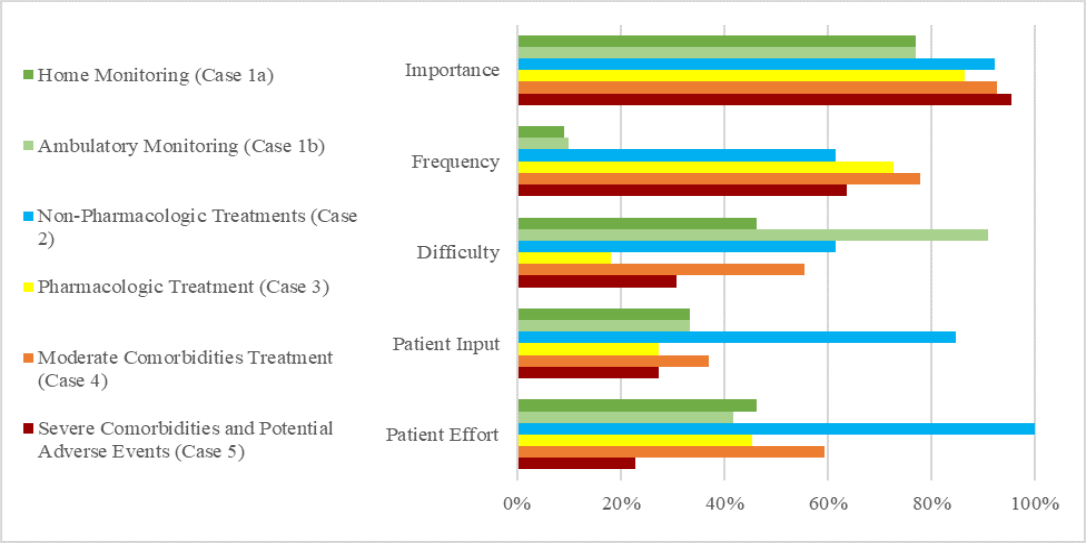

Figure 2. Percent of providers choosing the top 3 options for most important, frequent, difficult, and level of patient involvement

Figure 2 provides an example of provider attitudes towards the recommendations for five sample patient cases. In each case providers rated: their perceived importance, the frequency with which they are followed, the difficulty in following them, the amount of patient input, and the amount of patient effort. More than 80% of respondents rated the guidelines as important; but self-reported frequency of following guidelines ranged from 10-78%, with non-pharmacologic and the most complex responses followed least often. Patient input and effort were highest for non-pharmacologic treatments; these are largely self-managed. However, the amount of patient effort and input did not increase with the complexity of their situation.

Data sufficiency analysis. The data sufficiency paper (*Assessing data adequacy for high blood pressure clinical decision support: A quantitative analysis)* identified more than 158,000 patients with high blood pressure, of whom >100,000 had hypertension.

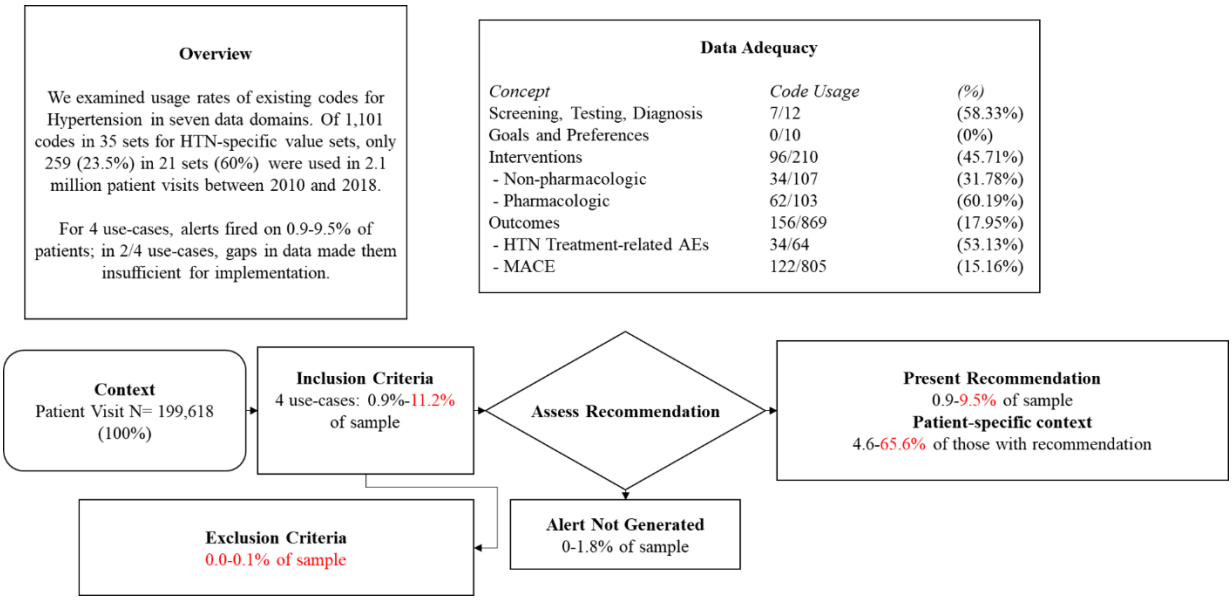

Figure 3. Graphical abstract of data sufficiency paper

The graphical abstract shows usage rates for codes in hypertension specific value sets. A substantial number of codes were rarely or never used, particularly around goals and preferences and non-pharmacologic interventions. Of the 35 initial value sets, 21 were able to be used with some adjustments.

In addition, four different use-cases – screening & monitoring, non-pharmacologic therapies, pharmacologic therapies, and adverse events - for recommendations were evaluated, and these generated alerts for 0.9 - 9.5% of the patient population. Of note, missing patient-specific context was seen in up to 65.6% of patients (for instance, no diagnosis of hypertension yet they were prescribed antihypertensive medications). With adaptation, components of each of the four use-cases were used in the implementation guide and application.

Outcomes. We had two major outcomes: production of the implementation guide and the COACH application itself.

Implementation Guide

The table of contents below describes the structure of the IG and its components. The IG is located at https://build.fhir.org/ig/OHSUCMP/htnu18ig/index.html. As can be seen, the IG contains all relevant

information about the premise, the logic, and the value sets, allowing future developers to download these components and use them in their own systems. It also has information about implementation into EHR systems based on our experience.

Table of Contents	Description
1 OHSU Hypertension IG Home Page	Provides a general overview of the tool; its purpose, clinical relevance, and key elements.
2 Background	Presents background information on hypertension and importance of clinical decision support tools.
3 Flow Logic	Contains flow diagrams and logic documentation for CDS pathways, including: 3.1 Initial Diagnosis and Monitoring 3.2 Very High Blood Pressure Warning - Safety 3.3 Adverse Events - Safety 3.4 Monitoring of Already Diagnosed Patient 3.5 Non-Pharmacologic Interventions 3.6 Pharmacology / Medicine-based
4 Detailed Specification	4.0 Describes the framework approach to implementing the CDS system. 4.1 Using CQF Ruler 4.2 Considerations for Epic Integration
5 Useful Downloads	Provides links to download the implementation guide, artifact definitions, and examples.
6 License	Terms and conditions for use, reproduction, and distribution
7 IG Change History	History of changes to the IG
8 Artifacts Summary	Specifies FHIR artifacts used in the application: terminology value sets, plan definitions, libraries, and other resources.

To implement, the IG-based recommendations are encoded as a PlanDefinition and associated Library FHIR artifacts. Logic is encoded using Clinical Quality Language (CQL) and incorporated into the associated Libraries. These resources are then loaded into a third-party system CQF Ruler, which itself is a HAPI FHIR server that implements clinical decision support logic via its CDS Services interface.
When the application triggers the execution of a recommendation for a patient, it bundles together relevant resources into what is known as a “prefetch” block, which is included in the CDS Services call to the CQF Ruler. The CQF Ruler receives these data and then executes the requested recommendation logic (CQL), generating any resultant Cards as needed. If any resources are required by the logic that aren’t provided by COACH via the “prefetch” block, CQF Ruler is able to make FHIR queries directly against the authenticated FHIR server.

COACH Application

For the application, the outcome is shown in 2 sections: first, a description and screenshots of the major components; and second, testing and feedback from the application. The COACH application's main screen (Figure 4) contains a basic patient information header, followed by blood-pressure readings displayed as a BP summary along with a line-chart depicting systolic and diastolic readings. Below the chart are listed the user's current blood pressure goal, any anti-hypertensive medications the user is currently taking, along with any recent adverse events recorded into their chart (identified as a specific set of Conditions). Below this are a set of recommendations that get executed for the user, which are generated by an auxiliary system (CQF Ruler) that processes Hypertension Implementation Guide resources and generates a series of recommendations in the form of Cards that can be displayed to the user, and which the user can interact with. These recommendations may involve setting goals, receiving counseling, or contacting their care team, for example.

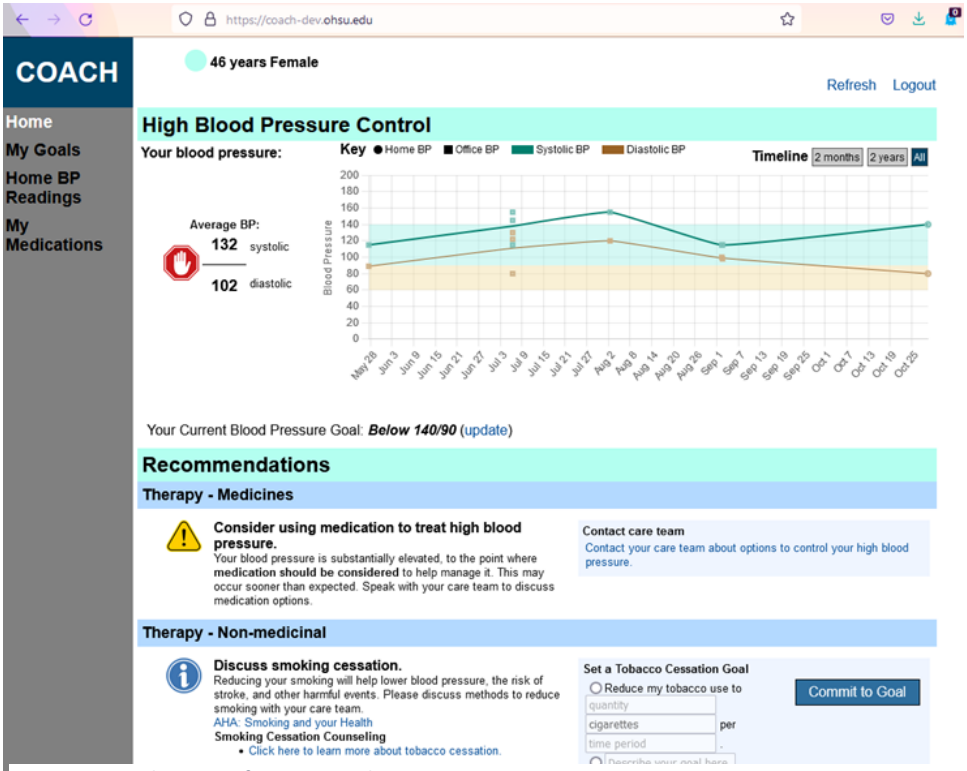

Figure 4. Initial screen of COACH application

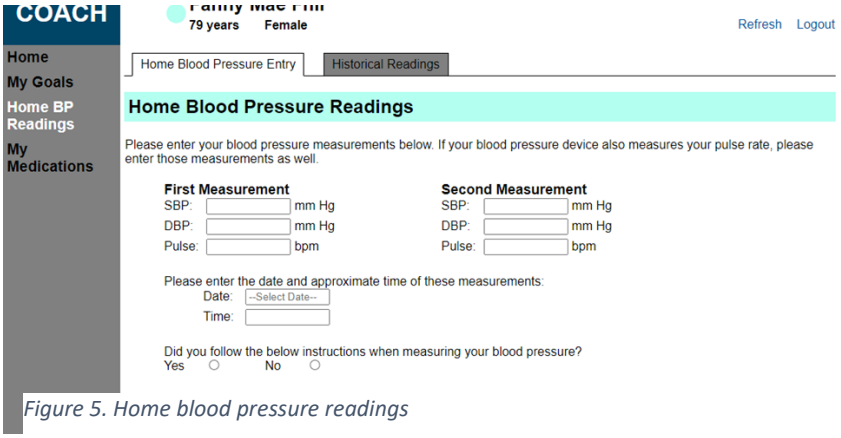

Figure 5. Home blood pressure readings

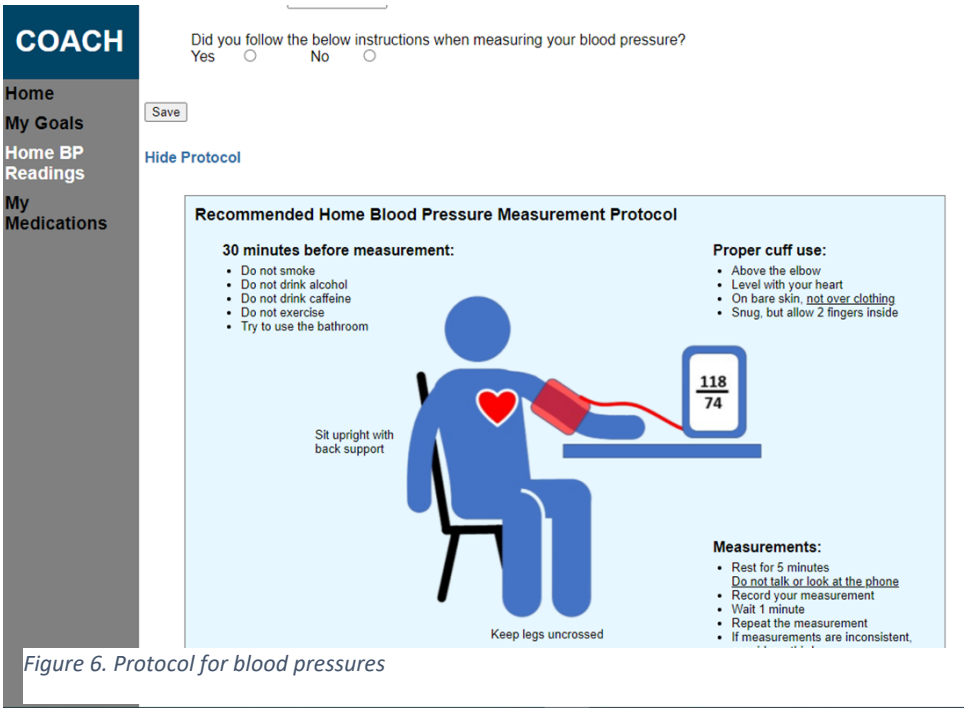

Figure 6. Protocol for blood pressures

Additional user interfaces in COACH include a screen where the user can enter Home Blood Pressure readings (Figure 5), which includes systolic, diastolic, and pulse readings, along with a timestamp, and a checkbox that the user can check which indicates whether or not they followed the prescribed blood pressure reading protocol (shown in Figure 6). The protocol was built from several different sources and made as simple as possible. It can be displayed or hidden by patient preference

There is also a screen (Figure 7) where the user can view their current medications and is categorized by Anti-Hypertensive medications and all Other Medications.

Receiving counseling and setting goals (Figure 8) for healthy behaviors are one of the most common recommendations. To follow-up on the goals over time, a separate page was created to both set blood pressure goals and to remind the patient about in progress and completed goals. One of the gaps identified by patients and providers was the ability to track structured goals over time.

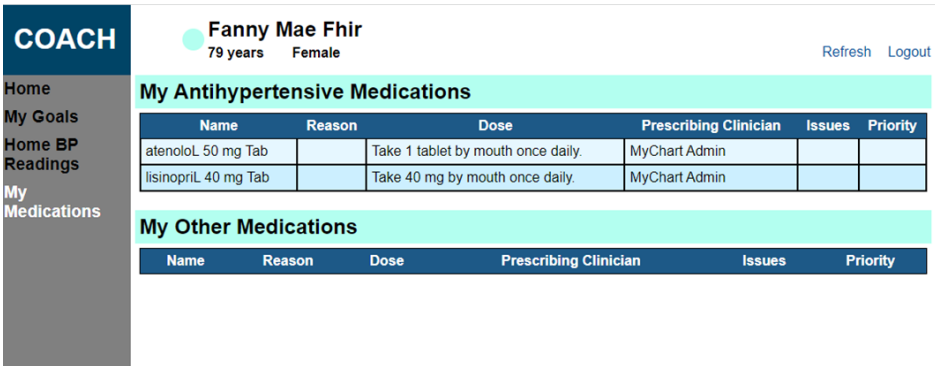

Figure 7. Medications

Dissemination and Collaboration. As part of the U18 mission, we made significant efforts to collaborate with AHRQ CDS Connect and other digital health groups. Although the Patient-Centered Clinical Decision Support (PCCDS) workgroup is not actively meeting, we did participate in the review done by a third party; we continue to meet monthly with the CDS Connect community and contribute to the meetings with presentations. We participated in the Clinical Decision Support Innovation Collaborative (CDSiC) initial kick-off and have presented at several related meetings. We also participated in the AMIA Fall Conference in 2021 to present this work and have met regularly with other U18 participants to share efforts. We have engaged

Figure 8 Goal setting and Counseling

with RTI International on the eCare Plan effort and have been sharing lessons learned from COACH with various grantees, including Dan Malone, Guilherme Del Fiol, Ken Kawamoto, Laura Marcial (for the CDS4CPM team), and Kristen Miller (MedStar Health).

We have published our CDS application and IG on open-source repositories on GitHub under our OHSUCMP account. Our initial implementation guide is available on GitHub (https://github.com/OHSUCMP/htnu18ig) as an open-source tool. We are ready to have this posted on CDS Connect as well; the CDSiC effort may be a good conduit to manage these efforts in the future.

Testing

Initial application testing was conducted with simulated patient data. Several different patient "personas" were designed to highlight different features and logical pathways of the application. These included test cases for insufficient blood pressure data, adverse reactions to new medications, triggers for behavioral goal setting, and exclusions for ineligible patients, among others. The simulated patients were created in a testing environment of the EHR system. The data was populated and then the COACH application was opened and/or refreshed. Proper behavior and defects were tracked with a spreadsheet.

Issues and defects were categorized into either "functionality", which covered errors, refresh and processing speed, data duplication, and accuracy of recommendations, or "interface", which covered usability issues like text phrasing, icons, placement, and color schemes. Issues were also assigned priority for fixing, which reflected urgency and complexity. The process of testing and fixing was iterative and went through several rounds until all major issues identified by the simulated data were resolved.

Next the application was tested by observing its performance with real patient data, this generated a new set of issues. Altogether so far, we have identified 9 issues with the interface and 41 with functionality. All of the interface issues have been fixed, but some of the functionality problems are still in progress, and a few other questions have been deferred for now. The in-progress issues are related to new things that have come up since we started testing with live patients; concerns about browser compatibility, errors and delays caused by larger than expected data volumes, and confirming that patient home blood pressure readings are being accurately saved back into Epic. The deferred issues are related to confirming functionality of the messaging feature in the live environment, improving the functionality and feedback around goal completion, and how to categorize some non-standard hypertension medications.

Issue Category	Number of Issues	Number Fixed	Deferred	In Progress
Functionality	41	30	3	8
Interface	9	9	0	0

Discussion

In brief, this application advanced interoperable, patient-centered clinical decision support through a set of initial analyses with patients, providers, and underlying data. We found that recommendations needed to be adapted for a number of factors: patient and provider preferences, values and attitudes; and limitations of the data itself. For patients, we found favorable attitudes towards controlling blood pressure through CDS applications. Most participants had monitored their blood pressure at home and considered blood pressure control a personal health priority. They also indicated a preference for more complete information presentation, including information about blood pressure history, clinician-endorsed goals, and potential pharmacologic treatments for hypertension. Social/relational information, such as what clinicians would recommend or what other patients would do, was deemed particularly trustworthy. We found an opportunity for CDS tools to encourage patient goal setting by presenting key options (e.g., smoking cessation) as suggested priorities, as patients indicated receptiveness to suggested prioritization of lifestyle changes in A/B testing.

CDS interventions can also be used to remind patients of their goals and promote adherence to those goals. Our survey results suggest that patients perceive they would act on information and recommendations displayed by the tool; however, significant previous work has shown that people overestimate their own actions.[35] By using displays that provide patients with more complete information about their blood pressure history and options for goal setting and treatment, patients may better trust the recommendations provided by the tool. Given the high priority that patients in the survey assigned to HBP management, CDS tools may be used to better engage patients in shared decision-making with their care team.

Providers found recommendations for hypertension guidelines to be important (>80%) and, in provided cases, selected at least one of a guideline's recommended options 70% of the time for diagnosis and monitoring; 100% for non-pharmacologic treatments; and 65% for pharmacologic treatments. Providers identified non-pharmacologic options as challenging and requiring the most patient effort and input; less patient input and effort was thought to be needed from pharmacologic approaches. Diagnosis and monitoring had several challenges – from the unreliability of office blood pressures to the burden on patients to monitor reliably and accurately.

Despite the small sample size, the respondents identified many areas where they would potentially diverge from the standards and the reasons for these decisions. Varying from the recommendations reflected variation between guidelines (lack of consensus) and specific patient characteristics (like social need, comorbidities, adherence issues, or frailty). Providers' response to increasing complexity was not to get more input from the patients or acknowledge their effort, but to decide to vary more frequently from guidelines. The challenges in managing guidelines with multiple comorbidities has been well studied; however, more recent work has highlighted the value in sharing the decision-making for these cases by eliciting patient priorities and values and deciding the best course of action together.[36, 37]

For data sufficiency, we found that it was possible to define 71 HBP recommendations and their required standardized data definitions. However, we had to develop or adjust 21 of 35 value sets for the data. Assessing the data quality in the EHR, we found that a substantial number of codes were

infrequently or never used. For instance, goals were uncoded, limiting the ability to personalize CDS for individual patients. Similarly, some interventions related to exercise, smoking cessation, and alcohol use had limited mapping in the EHR, leading to 2 of 4 of the test use-cases yielding high firing rates. Non-pharmacologic recommendations, for instance, would fire on 9.5% of patients; in a patient-facing application, this high rate may be appropriate, but care teams would likely experience significant alert fatigue.[38] Pharmacologic recommendations would fire on 0.9% of patients with HBP, indicating potential data adequacy. These mixed results show implementation of CDS for HBP must have prior data quality and logic testing to avoid harm and alert fatigue.

These findings, while mixed, are improved from earlier CDS efforts, where every implementation had to be tailored to local data. Preferred terminologies (SNOMED, LOINC, and RxNORM) are now common in EHRs, even if data mapping is variable. Adapting based on data adequacy testing can improve CDS; for instance, the majority of data were encoded to CPT and ICD rather than SNOMED, requiring developers to query both and perform extension mappings themselves. Patient-related concepts – goals, preferences, self-management interventions – had low standardization and use.

This work advances the literature in two ways: first, by implementing a standard method to test data adequacy or sufficiency for CDS. Second, by exploring some of the potential sources of alert fatigue. Based on our results, incomplete data would lead to much higher alerting rates in two use-cases and would limit alerting to a small number in the other two use-cases.[39] Implementation in either provider- or patient-facing CDS would have to account for the low rates of exclusions and patient-specific context/extenuating circumstances recorded in the data to mitigate the frequently reported alert fatigue from over-alerting. Specific data mapping by the local implementing site or substantial structured data collection would be required for some use-cases; these processes are costly and time-intensive. Opportunities to gather the data directly from patients may reduce costs, as many of the missing elements are based on patient experience.[41] Others have shown positive feedback loops in managing HBP can be effective; Ralston et al showed secure messaging between patients and pharmacists or care managers improved BP; while Benkert et al. showed rapid feedback cycles improved BP control but highlighted the risk of message fatigue.

Gaining end-user perspectives and preferences is fundamental to user-centered design, particularly for new technologies such as shareable and interoperable CDS. These data are informing the designs of our provider-facing CDS tool, which we anticipate will increase the likelihood of provider adoption. Using this survey method in which providers ranked preferences for guideline-based recommendations given patient scenarios has provided important insights as to how providers perceive the benefits of some recommendations over others when weighed against specific patient scenarios. We encourage researchers and developers to build on this approach so to better inform CDS designs.

Furthermore, surveys like ours may be sufficient for designing CDS applications, however we encourage informaticians to incorporate more advanced methods. For example, methods from cognitive science may better elucidate user perceptions and replicate real-world decisions around guideline-based care for hypertension management.

Implementers, innovators, and researchers are welcome to use our generated sets and test instructions as they build their own tools or check their own data, available at our GitHub site (https://github.com/mattStorer/OHSUHTNU18/tree/master/docs/resources/dataSufficiency). Future work will be to incorporate these lessons into CDS tools – both on the patient- and provider-facing side.

The state of external applications to improve blood pressure control is still in flux, with applications that combine data and knowledge together in limited use. Given current alerting rates would be extremely high for two of our use-cases, future developers should understand many alerts are likely to be inaccurate, based on incomplete data, and a data completion effort must be a part of any future work. However, burn-out of care teams limit further structured data entry, [47, 48] requiring more creative solutions.

Conclusions

In all, this digitally literate group of patients and providers were ready to engage with CDS tools and provided substantial guidance as to the optimization of these tools through meaningful visualizations with context provided through evidence and from trusted groups. Next steps include expanding the population to those with lower digital literacy and testing the visualizations, reminders, and tailored messages in the real world through a pragmatic trial. However, providers had highly variable approaches to high blood pressure management and were accepting of patient-facing CDS tools, but emphasized the importance of CDS recommendations that capture the complexity and nuance of the recommendations. The results from our survey are informing the project team's decisions around designing SMART-on-FHIR CDS that supports provider and patient needs for hypertension management.

Finally, for data sufficiency, our work provides a framework to test data adequacy across value sets, between key populations, and across use-cases. Gaps in data adequacy across these examples were common and must be addressed prior to implementing CDS for HBP. The results of these surveys, interviews and analyses have been used to inform the development of a new clinical decision support tool for hypertension diagnosis and treatment we call COACH and the initial implementation guide.

Significance and Implications

The impact of these findings on CDS systems is substantial. First, presenting the recommendations in certain situations – recommending non-pharmacologic therapy – could be highly successful if issues around workflow and patient input could be addressed. Second, many providers asked for visualization tools and guidance on consensus or agreement, which could be presented as part of the recommendations to help guide the discussions. Third, support for the challenges of home monitoring to get reliable information for diagnosis and overcoming these challenges could address a major gap. Finally, even when there is not consensus from guidelines, prioritization is still possible. Highlighting potential patient factors that could aid in prioritization, while referencing the most frequently chosen options, could improve personalization and social trust, both factors that impact behavior and could increase adherence. Gaining end-user perspectives and preferences is fundamental to user-centered design, particularly for new technologies such as shareable and interoperable CDS.[44] These data continue to inform the design of our provider-facing CDS tool, which we anticipate will increase the likelihood of provider adoption. Using this survey method in which providers ranked preferences for guideline-based recommendations given patient scenarios has provided important insights as to how providers perceive the benefits of some recommendations over others when weighed against specific patient scenarios. We encourage researchers and developers to build on this approach so to better inform CDS designs.

Furthermore, surveys like ours may be sufficient for designing CDS applications, however we encourage informaticians to incorporate more advanced methods. For example, methods from cognitive science

may better to elucidate user perceptions and replicate real-world decisions around guideline-based care for hypertension management.[45]

List of Publications

Patient perspectives on enhancing clinical decision support for high blood pressure control (Journal of General Internal Medicine, in-press)
Provider perspectives on patient- and provider-facing high blood pressure clinical decision support (Journal of Applied Clinical Informatics, in-press)
Assessing data adequacy for high blood pressure clinical decision support: A quantitative analysis (Journal of Applied Clinical Informatics, Aug. 12, 2021) doi: 10.1055/s-0041-1732401

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